#### PATENT APPLICATION

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

**Group 1643** 

Madhwa H.G. Raj et al.

Examiner Duffy, Bradley

Serial No. 10/797,690

Confirmation No. 7199

Filing Date: March 10, 2004

For:

Treatment of Prostate Cancer (File Rai 02M27.1)

#### RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

This paper is submitted in response to the December 7, 2006 restriction requirement.

No amendments are presented.

Applicants are paying a fee of \$60 by credit card, through Private PAIR, as a small entity, to extend the date for response from January 7, 2007 to February 7, 2007. If any additional extension of time is required, please consider this paper a petition for the total extension of time required, and please refer to the Deposit Account Authorization previously filed with this application.

#### CERTIFICATE

I hereby certify that this Response to Restriction Requirement is being transmitted to the United States Patent and Trademark Office over the Internet, via Private PAIR, on January 18, 2007. I hereby also certify that the \$60 fee for extension of time is being paid by credit card, through Private PAIR, on January 19, 2007.

> Registration No. 33,451 January 19, 2007

Applicants respectfully traverse the restriction requirement, for the reasons given below.

#### **Provisional Election**

In response to the December 7, 2006 restriction requirement, Applicants provisionally elect with traverse Group IV, which the December 7, 2006 restriction requirement identified as including Claim 10.

## **Linking Claims**

The December 7, 2006 restriction requirement identified certain linking Claims.

As the December 7, 2006 restriction requirement recognized (p. 4, par. 5), and as provided in M.P.E.P. § 809, the linking claims are considered part of, and must be examined with, the elected invention.

For example, the Office identified Claims 9 and 22 as linking Groups IV-VI.

Thus, at a minimum, Claims 9 and 22 should be examined along with Claim 10 of provisionally elected Group IV.

As the December 7, 2006 restriction requirement also recognized (p. 4, par. 5), and as also provided in M.P.E.P. § 809, once any linking claim is found to be allowable, the restriction requirement between the linked inventions must be withdrawn, and the non-elected claims that were "linked" by the linking claim must then be rejoined and fully examined.

Thus, if either Claim 9 or Claim 22 is found to be allowable in substance, then at a minimum, consistent with the Office's own grouping of the Claims, Claims 11 and 12 must then be fully examined.

Please note that the above conclusions would apply even if none of the restriction requirements were otherwise withdrawn. Even if all restriction requirements were otherwise maintained, it would still be the case that linking Claims 9 and 22 must be examined along with provisionally elected Group IV (Claim 10). And even if all restriction requirements were maintained, it would still be the case that the linked Claims 11 and 12

must be rejoined and fully examined once either linking Claim 9 or linking Claim 22 is found to be allowable in substance.

Additionally, for the reasons given below, it is respectfully submitted that all restriction requirements should be withdrawn in any event.

## **Traversal of Restriction Requirement**

There are two separate criteria that must both be satisfied for a restriction requirement to be proper:

(A) The inventions must be independent or distinct as claimed;

and

(B) There would be a serious burden on the examiner if restriction is not required.

M.P.E.P. § 803, part (I).

The Office has not shown that condition (A) is satisfied for any pair of Groups. The Office has only shown that condition (B) is satisfied for some pairs of Groups. Unless both conditions are satisfied for all pairs of Groups, restriction may not be required among any of the Groups.

# The Office Has Not Established the Distinctness of any of the Groups.

The Office has not carried its burden of showing that any of the 12 Groups are distinct from one another.

In order to properly justify a proposed twelve-way restriction requirement, the Office would need to demonstrate that each pair of Groups is distinct. In other words, the Office has the burden of showing each of the following:

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Group I is distinct from Group II,
Group I is distinct from Group III,
Group I is distinct from Group IV,
...
Group I is distinct from Group XII,
Group II is distinct from Group III,
Group II is distinct from Group IV,
...
Group II is distinct from Group XII,
Group III is distinct from Group XII,
Group III is distinct from Group XII,
Group III is distinct from Group XII,
...
Group VI is distinct from Group X,
... and
Group XI is distinct from Group XII.
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The Office would thus need to provide a total of 11 + 10 + 9 + 8 + ... + 3 + 2 + 1 = 66 demonstrations of distinctness between pairs of Groups in order to justify a twelve-way restriction requirement.

However, the Office has in fact made no demonstrations of distinctness at all. The Office has not justified restriction for even one pair of Groups, much less for all 66 possible pairings of twelve Groups.

Page 5 of the December 7, 2006 Restriction Requirement discusses various ways in which some of the Groups were found to differ from one another. Most of this discussion was extremely general. Indeed, several of the twelve Groups were not specifically mentioned anywhere at all in the Office's general discussion. Such generalities do not satisfy the specific requirements of M.P.E.P. Chapter 800.

Without necessarily agreeing with every statement on page 5 of the December 7, 2006 Restriction Requirement, the Applicants can certainly agree with the general observation that the scope of any two claims in a patent application will, in general, differ. This observation should not be the least bit surprising. Indeed, the doctrine of "claim

differentiation" is based on the premise that a patent applicant will normally write each claim so that it has a scope that differs, to some degree, from the scope of every other claim presented in the application.

Simply observing that some claims have a different scope from other claims does not justify restriction. Yet, that is basically all that page 5 of the December 7, 2006 Restriction Requirement asserts. The Office Action made no attempt to explain whether or how any of the observed differences were related to any of the specific criteria set forth in Chapter 800 of the M.P.E.P. to define "distinctness" for purposes of restriction.

To justify a restriction requirement, the Office has the burden of showing, not just that different claims have differing scope, but instead that the several groups of claims are "distinct" within the contemplation of Chapter 800 of the M.P.E.P. With all respect, the December 7, 2006 Restriction Requirement does not even purport to make such a showing. None of the particular sections or subsections of Chapter 800 of the M.P.E.P. that specifically address what "distinctness" means in various contexts was cited anywhere in the Restriction Requirement.

It does not suffice to observe that differences exist between the claims. The Office instead carries the higher burden of demonstrating that different groups of claims are "distinct" from one another, within the contemplation of specific sections of Chapter 800 of the M.P.E.P. The Office has not carried this burden. The restriction requirement should be withdrawn.

Essentially similar observations were made previously, in the Applicants' October 16, 2006 Response, replying to the earlier, now-vacated July 11, 2006 Restriction Requirement. The Applicants have previously explained the Office's burden to show distinctness of the groups under Chapter 800 of the M.P.E.P. However, the December 7, 2006 Restriction remained silent on this point. The Office has not carried its burden.

# In Some Instances, the Office Has Also Not Satisfied Its Burden of Showing That There Would be a Serious Burden in Examining the Groups together.

Strictly in the alternative, even if the Office had demonstrated that the Groups were distinct from one another (and, for the reasons just given, the Office has not done so),

restriction would still not be justified in many cases, because the Office has not shown that there would be a serious burden in examining the Groups together. "Serious burden" is also required to justify restriction. See M.P.E.P. § 803.

In particular, the Office has acknowledged that Groups II and III are identically classified, namely, in class 514, subclass 44. Thus the Office has acknowledged that there would be no burden in examining Groups II and III together – even if, for the sake of argument, the Office had shown Groups II and III to be distinct. For this reason alone, at least the restriction requirement between Groups II and III should be withdrawn.

Likewise, the Office has acknowledged that Groups IV through IX are identically classified, namely, in class 424, subclass 184.1. Thus the Office has acknowledged that there would be no burden in examining Groups IV through IX together – even if, for the sake of argument, the Office had shown Groups IV through IX to be distinct. For this reason alone, at least the restriction requirement among Groups IV through IX should be withdrawn.

## The Conditional Election of Species Requirement

On pages 6-8 (pars. 8-10) of the December 7, 2006 Office Action appeared a conditional election of species requirement. The conditional election of species requirement applied only "[i]f applicant elects any of Groups I-III . . . . " (page 7).

Because Applicants have provisionally elected Group IV, and because this conditional requirement applied only if one of Groups I-III was elected, it is respectfully submitted that the election of species requirement is moot, and that no further response is required from the Applicants.

#### Conclusion

The restriction requirement should be withdrawn in its entirety, and all Claims should be examined on their merits.

The Examiner is respectfully advised that if the restriction requirement should be repeated, then it is the Applicants' present intention to file a formal Petition to seek review of the propriety of the restriction requirement.

Allowance of Claims 1-23 at an early date is respectfully requested.

Respectfully submitted,

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January 19, 2007